United States Food and Drug Administration

Tobacco Product Standard for Nicotine Yield of Cigarettes and
Certain Other Combusted Tobacco Products

OMB Control No. 0910-NEW
RIN 0910-AI76

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) rulemaking entitled "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products".

Section 907 of the Food Drug and Cosmetics Act (FD&C Act) authorizes FDA to adopt tobacco product standards, including product standards that include provisions for nicotine yields; for the reduction or elimination of other constituents (including smoke constituents) or harmful components; respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of tobacco products; for the testing of tobacco products; and for restricting the sale of tobacco products to the extent consistent with section 906 (21 U.S.C. 387f) (section 907(a)(3), (a)(4)(A)(i) to (iii), and (a)(4)(B)(i) to (ii) and (iv) to (v)). The FD&C Act also establishes FDA's authority to require tobacco product manufacturers to establish and maintain records in section 909 (21 U.S.C. 387i); authority related to adulterated and misbranded tobacco products in sections 902 and 903 (21 U.S.C. 387b and 387c); authority regarding premarket review of new tobacco products in section 910 (21 U.S.C. 387j); authority related to prohibited acts in section 301 (21 U.S.C. 331); and FDA's rulemaking and inspection authorities in sections 701 and 704 (21 U.S.C. 371 and 374).

The proposed rule, if finalized, would establish requirements related to provisions for nicotine yields and for the reduction or elimination of other constituents (including smoke constituents) or harmful components (section 907(a)(3)(A) and (4) of the FD&C Act). FDA is proposing to limit nicotine yield by setting a maximum nicotine content level for finished cigarettes and certain other finished combusted tobacco products not to exceed 0.70 mg of nicotine per gram of total tobacco.

2. Purpose and Use of the Information Collection

The information collection requirements in the proposed standard would apply to tobacco product manufacturers, which means any person, including a repacker or relabeler, who (1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States. Specifically, the information collection would apply to manufacturers of cigarettes (other than noncombusted cigarettes, such as heated tobacco products that meet the definition of a cigarette), cigarette

tobacco, roll-your-own (RYO) tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding "premium cigars"), and pipe tobacco (other than waterpipe tobacco).

FDA recognizes that many of the proposed provisions of the proposed rule are in accordance with the quality control and manufacturing practices that manufacturers have already adopted on a voluntary basis. Based on FDA's subject matter expertise and industry data, we recognize that between 85 and 90 percent of all cigarette production is conducted by large manufacturers. We also find that the other tobacco product categories, such as non-premium cigars, pipe, and RYO tobacco, have similar levels of market concentration. We assume that large tobacco product manufacturers represent the bulk of tobacco product production capacity and so represent the majority of recordkeeping burden.

3. Use of Improved Information Technology and Burden Reduction

Much of the recordkeeping (establishing and maintaining) of the information within this collection is part of standard and customary business practices of tobacco manufacturers. As such, FDA is allowing respondents to define many of the parameters and frequencies related to the creation and retention of the information under this collection. This includes the use of electronic and automated systems that many respondents already use. Based on FDA subject matter expertise and inspections data, we find that almost all manufacturers already have in place a system to establish and maintain these records in an electronic format. We expect 99% of respondents to keep their records electronically.

There currently is no planned guidance for this rule. However, if the rule is finalized and there are consistent matters or questions from industry, a guidance document may be issued if necessary.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. There is no reliable information available elsewhere that can be used for these purposes. In particular, the Centers for Disease Control and Prevention is not requiring records; related to batch testing, sampling plans and sampling procedures, analytical test method validation, identification the production batch of a particular finished product that has been released for distribution and manufacturing controls; that would be established and maintained in response to the proposed rule, if finalized. Because FDA is the only Federal agency with the authority to adopt tobacco product standards and require tobacco product manufacturers to establish and maintain tobacco product records under the FD&C Act, duplication by other Federal agencies is unlikely.

5. Impact on Small Businesses or Other Small Entities

We project impact to small businesses from the standpoint of how businesses make decisions to remain in the market, assuming small businesses of all sizes continue to operate and comply with this product standard. FDA is allowing respondents to define many of the parameters and frequencies related to the creation and retention of the information under this collection to assist in minimizing the impact and burden to respondents.

In addition, to help minimize burden for small businesses, CTP's Office of Small Business Assistance (OSBA) offers resources online to help businesses understand and comply with tobacco regulatory requirements. Small tobacco product manufacturers can visit the following

webpage to learn more about OSBA and the resources available for small businesses: https://www.fda.gov/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry.

6. Consequences of Collecting the Information Less Frequently

The proposed regulation would establish recordkeeping requirements related to a tobacco product standard that would regulate the nicotine yield of cigarettes by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products. Each year, 480,000 people die prematurely from a smoking-attributable disease. Nearly all these adverse health effects are ultimately the result of addiction to the nicotine in combusted tobacco products, leading to repeated exposure to toxicants from those products. In the event of a nonconforming product, which would render the product adulterated or misbranded under the FD&C Act, this information would help determine the product's history (e.g., batch testing records) and assist respondents and FDA in a nonconforming tobacco product investigation and the need for any corrective actions that stem from such investigation. By imposing this nicotine product standard FDA can thereby assure that the public health is protected and that tobacco products comply with the requirements in chapter IX of the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

We are publishing a proposed rule in the *Federal Register* inviting public comment on the proposed information collection in accordance with 3508(d).

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, we consulted with the FDA Privacy Office to ensure appropriate handling of information collected. This proposed information collection request will collect personally identifiable information (PII) in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). FDA has further determined that although PII will be collected the collection, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA will not use name or any other personal identifier to retrieve records from the information collected. FDA will minimize the PII to be collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade, and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden

21 CFR Section or Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 1160.12 Product Testing	143	50.84	7,270	9	65,430
§ 1160.14 Analytical Test Method	143	4	572	1	572
§ 1160.16 Sampling Plan	143	4	572	1	572
§ 1160.18 Procedures for Nonconforming Tobacco Products and Related Investigations; Procedures for Control and Disposition of Nonconforming Tobacco Products	143	1	143	14	2,002
§ 1160.30 Package Label Requirements (Manufacturing Code)	143	4	572	7	4,004
§ 1160.32 Recordkeeping Requirements (Batch Testing Records)	143	50.84	7,270	6	43,620
Total Annual Burden					116,200

Table 1 displays the recordkeeping burden associated with this proposed rule. Included in this estimate is the recordkeeping burden for establishing and maintaining records regarding the results of testing conducted on each batch to determine conformance with the proposed standard, sampling plans and sampling procedures, and records related to manufacturing controls.

FDA's burden estimates are based on CTP's Tobacco Registration and Listing Module Next Generation (TRLM NG) data and Dun & Bradstreet firm data (D&B). The requirements in the Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products proposed rule would apply to both domestic and foreign manufacturers of finished tobacco products that are distributed or sold in the United States. We estimate the number of affected entities, by tobacco product category and size of operation group. We estimate that there are a total of 143 entities potentially affected by the proposed rule (domestic manufacturers and importers of impacted tobacco products, including 133 manufacturers and importers of cigarettes, cigars, pipe tobacco, and RYO tobacco and 10 dual operation facilities that manufacture both combusted and noncombusted products). For purposes of the PRA estimates, FDA used the entities affected and a weighted average of the median hours to calculate the respondents and total burden hours.

We estimate a total of 7,270 batches per year are required to be tested under § 1160.12 (product testing). Based on information from inspections and other FDA subject matter expertise, including typical batch sizes and projected combusted tobacco production by year, FDA estimates that there will be 50.84 records per recordkeeper with 9 hours of average burden per recordkeeping. FDA assumes respondents will establish a total of 7,270 annual records for a total of annual 65,430 hours.

Based on information from inspections and other FDA subject matter expertise, we expect that core blends are the products that manufacturers will choose to reformulate to meet the product standard. Manufacturers would incur a burden to establish an analytical test method and sampling plan for each reformulated core blend. FDA experts assume that each manufacturer, on average, utilizes four different core blends per tobacco category that they manufacture.

Under § 1160.14 (analytical test method), respondents would determine an analytical test method to use for complying with the product standard. During validation of the analytical test method within the laboratory to be used, the respondent would record and collect the data generated and maintain these records. FDA estimates there will be 4 records per recordkeeper with 1 hour of average burden per recordkeeping and respondents will establish a total of 572 annual records for a total of annual 572 hours.

Under § 1160.16 (sampling plan), FDA estimates there will be 4 records per recordkeeper with 1 hour of average burden per recordkeeping. FDA assumes respondents will establish a total of 572 annual records for a total of annual records for a total of annual 572 hours.

Under § 1160.18 (procedures for nonconforming products), FDA assumes there will be 1 record per recordkeeper with 14 hours of average burden per recordkeeping for a total of 143 annual records and a total of annual 2,002 hours. This estimate is based on information from inspections and FDA experience in developing good manufacturing practices in non-tobacco industries.

Proposed § 1160.30 would require manufacturers to apply a manufacturing code to the packaging and label of tobacco products. Based on FDA subject matter expertise and market

tracking information, we find that almost all manufacturers already apply a manufacturing code to their products. FDA assumes 4 records per recordkeeper with 7 hours of average burden per recordkeeping, and a total of 572 annual records for a total of annual 4,004 hours.

Under § 1160.32 (batch testing records), FDA assumes 50.84 records per recordkeeper with 6 hours of average burden per recordkeeping. This estimate is based on establishing the format and maintaining batch test records for detailed recordkeeping requirements, including English translation and accessibility, that are necessary to confirm that finished tobacco products are in compliance with the proposed product standard. FDA assumes that respondents will maintain a total of 7,270 annual records for a total of annual 43,620 hours.

FDA expects the additional one-time (i.e., occurring only in the first year) reporting burden for the information collection that will result from this rule, to be as follows:

Table 2.--Estimated One-Time Reporting Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Review and familiarization with the rule	1,465	1	1,465	10	14,650

Based on FDA subject matter expertise, we assume that all entities affected by this proposed rule would spend time to read and understand the rule, resulting in a one-time reporting burden. FDA estimates that there will be 293 entities and 5 individuals at each entity that will read the final rule. It is estimated that each respondent will spend up to 10 hours reading and understanding the rule for a total of 14,650 one-time burden hours.

Per the requirements of this proposed rule, FDA estimates the total burden will be 130,850 hours (116,200 + 14,650).

For the purpose of ROCIS entry the total number of respondents and total hours has been divided by 3 to account for annualizing both totals.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is $9,624,111.90.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Chemical Technicians	54,435	$79.54	$4,329,759.90
Office and Administrative Support	61,765	$49.20	$3,038,838.00
Management Occupations	7,325	$147.76	$1,082,342.00
Legal Occupations	7,325	$160.16	$1,173,172.00
Total	130,850		$9,624,111.90

Estimates of the cost of the annual burden are based on mean hourly wage rates, which have been doubled per hour to account for benefits and overhead. These rates are derived from the Department of Labor's Bureau of Labor Statistics for Tobacco Manufacturers (The Bureau of

Labor Statistics (BLS) May 2023 data - NAICS 312200 - https://www.bls.gov/oes/2023/may/naics4_312200.htm#17-0000).

We estimate that 75% of the total burden hours associated with §§ 1160.12, 1160.14, 1160.16, 1160.18, and 1160.30 will be attributed to chemical technicians (75% of 72,580 burden hours). Our estimates for chemical technicians (occupation code: 19-4031) are based on a mean hourly wage rate of $39.77, doubled to $79.54 per hour to account for benefits and overhead.

We estimate that 25% of the total burden hours associated with §§ 1160.12, 1160.14, 1160.16, 1160.18, and 1160.30 (25% of 72,580 burden hours) and 100% of the total burden hours associated with § 1160.32 will be attributed to office and administrative support. Our estimates for office and administrative support (occupation code: 43-0000) are based on a mean hourly wage rate of $24.60, doubled to $49.20 per hour to account for benefits and overhead.

We estimate that 50% of the one-time burden hours associated with reading and understanding the rule will be attributed to management occupations. Our estimates for management occupations (occupation code: 11-0000) are based on a mean hourly wage rate of $73.88, doubled to $147.76 per hour to account for benefits and overhead.

We estimate that 50% of the one-time burden hours associated with reading and understanding the rule will be attributed to legal occupations. Our estimates for legal occupations (occupation code: 23-0000) are based on a mean hourly wage rate of $80.08, doubled to $160.16 per hour to account for benefits and overhead.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no additional capital costs associated with this collection of information.

The proposed provision § 1160.12 (batch testing), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Batch testing is conducted either by the manufacturer in-house or by a 3rd-party accredited laboratory. If sent to a 3rd-party laboratory, we do not expect any capital, operating, or maintenance costs associated with batch testing to be incurred by the manufacturer. We expect a manufacturer would only test their products in-house if they already possess an in-house laboratory accredited to conduct scientific tests. We would not anticipate capital, operating, or maintenance costs for these in-house laboratories as capital and maintenance are components of maintaining accreditation. We do not expect any manufacturers currently without an in-house laboratory to newly establish an in-house accredited laboratory as a result of this product standard.

The proposed provision § 1160.14 (analytical test method), is also part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Manufacturers are already required to submit test results for relevant harmful and potentially harmful constituents (HPHCs) as part of premarket submissions, of which nicotine is one. As the establishment and use of analytical testing is already generally required for premarket

submissions, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.16 (sampling plans), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Manufacturers already routinely conduct analytical testing to check for consistency in their finished products. To conduct such testing, manufacturers would have needed to establish a sampling plan to generate a representative sample of their product for testing. As such, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.18 (nonconforming tobacco products), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Based on FDA subject matter expertise and inspections, we find that almost all manufacturers already check for consistency and conformance of their products and rework product as necessary to supply information for internal quality checks and distribution purposes, we do not anticipate capital, operating, or maintenance cost from these provisions.

The proposed provision § 1160.30 (manufacturing code labeling), is part of standard and customary business practices of tobacco manufacturers. As such, there are no capital costs or operating and maintenance costs associated with this collection of information. Based on FDA subject matter expertise and industry information, we find that almost all manufacturers already apply a manufacturing code to their products. Because a manufacturing code also supplies information that the manufacturer needs for internal quality and distribution purposes (standard and customary practices), we do not anticipate additional capital, operating, or maintenance cost from these provisions.

14. Annualized Cost to the Federal Government

These activities will be administered through existing resource allocations supported by user fees. To the extent that review of the retained records would generally occur as part of FDA's routine or for cause establishment inspection activities, the recordkeeping will also support FDA's regulatory compliance activities and help reduce inspection and legal costs. CTP estimates that 13 to 30 full-time equivalent (FTE) employees would be required for these activities in the first two years after the effective date of this proposed standard, if finalized. From year three onward, CTP estimates that 11 to 23 FTEs would be required for ongoing enforcement. We estimate a cost per FTE in 2023 equaling $320,080 inclusive of benefits and other indirect costs. For PRA purposes we calculated the midpoint of these FTEs and divided by three for a total of 21 FTEs per year. We estimate 25% of an FTE's time would involve records inspection and review. FDA anticipates this recordkeeping will comprise 1% of the FTEs record inspection and review time. Therefore, we estimate $16,804.20 net annual opportunity cost to the Federal government based on this rulemaking for the first three years. We describe this as an opportunity cost because this cost is a reallocation of CTP's existing resource allocations to enforce the proposed product standard, if finalized.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

If finalized, we expect the rulemaking to result in 130,850 hours and 17,864 recordkeeping/responses. We expect the initial burden results from reading and understanding the rule to incorporating the new requirements.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.